REMARKS

Applicants are amending this Application to make specific reference that this Application is a continuation-in-part application of, and to claim priority under 35 U.S.C. 119(e) to, provisional application serial No. 60/179,910, filed February 3, 2000.

This Amendment and Response responds to the Office Action mailed February 27, 2002. Claims 1-59 are pending in the Application. By this Amendment and Response, claims 10, 21, 26, 40, 47, and 50 have been cancelled, without prejudice to their resubmission. Claims 2, 3, 5, 6, 11-20, 22, 27-36, 41-46, 48, 49, and 52-59 have been amended. Claims 60-64 have been added. No new matter has been added. Claims 1-9, 11-20, 22-25, 27-39, 41-46, 48-49, and 51-64 remain pending after this Amendment and Response. The amendments are not intended in any way to limit the scope of the claimed invention or its equivalents.

A. Objections Due To Informalities

The Examiner objected to claims 15, 31, and 34 because of informalities relating to certain typographical and grammatical errors. Applicants have amended these claims in the manner suggested by the Examiner in order to correct these errors. Applicants respectfully submit that these amendments resolve the Examiner's objections.

B. Rejections Under 35 U.S.C. § 112

Claims 2, 3, 5, 6, 11-15, 17, 18, 20, 22, 27-30, 32, 33, 35, 36, 41-44, 46, 47, 49, 53, 55, 57, and 59 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Examiner rejected:

(1) dependent claims 2, 3, 5, 6, 17, 18, 20, 22, 32, 33, 35, and 36 on the grounds that the claims recited the limitations "the geometric mean T_{max}" and "the arithmetic mean T_{max}" and that these limitations lacked sufficient antecedent basis;

(2) dependent claims 11-14, 27-30, 41-44, and 47 on the grounds that the claims recited the limitations "the geometric mean AUC(0-24hr)" and "the arithmetic mean AUC(0-24hr)" and that these limitations lacked sufficient antecedent basis;

(3) dependent claim 15 on the grounds that the claim recited the limitation "the allergic reaction" and that this limitation lacked sufficient antecedent basis;

(4) dependent claims 46, 53, 55, 57, and 59

(i) on the grounds that the claims recited limitations regarding "the arithmetic mean steady state maximum plasma concentration (C_{max})" and that these limitations lacked sufficient antecedent basis and

(ii) on the grounds that the claims recited limitations regarding various plasma concentration parameters that were inconsistent with limitations in the independent claims from which claims 46, 53, 55, 57 and 59 respectively depend; and

(5) dependent claim 49 on the grounds that claim 49 recites limitations regarding the "arithmetic mean steady state maximum plasma concentration (C_{max})," the "arithmetic mean time to maximum plasma concentration (C_{max})," and the "area under the concentration time curve" and that these limitations lack sufficient antecedent basis.

Applicants respectfully disagree with the Examiner's rejection of claims 2, 3, 5, 6, 11-15, 17, 18, 20, 22, 27-30, 32, 33, 35, 36, 41-44, 46, 47, 49, 53, 55, 57, and 59. Nevertheless, in order to avoid unnecessarily delaying the issuance of a patent, these claims have been amended to address the Examiner's concerns.

Dependent claims 2, 3, 5, 6, 17, 18, 20, 22, 33, 35, and 36 have been amended to clarify that the respective geometric and arithmetic mean T_{max} limitations simply recite times at which the recited geometric or arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine or 3-OH-

desloratadine is produced. Each independent claim from which claims 2, 3, 5, 6, 17, 18, 20, 22, 33, 35, and 36 respectively depend recites a geometric or arithmetic mean steady state maximum plasma concentration (C_{max}), which provides an antecedent basis for the respective amended dependent claims. Applicants also have amended the article preceding the geometric and arithmetic mean T_{max} limitations in claims 2, 3, 5, 6, 17, 18, 20, 22, 33, 35, and 36 from "the" to "a" or "an."

Dependent claims 11-14, 27-30, and 41-44 have been amended to clarify that the respective geometric and arithmetic mean AUC (0-24hr) limitations simply recite areas under curves generated by a plot of the recited plasma concentration of desloratadine or 3-OH-desloratadine over time. The plasma concentration of desloratadine or 3-OH-desloratadine is a parameter recited in each of the respective independent claims from which claims 11-14, 27-30, and 41-44 depend. Applicants also have amended the article preceding the geometric and arithmetic AUC (0-24hr) limitations in claims 11-14, 27-30, and 41-44 from "the" to "a" or "an."

Dependent claim 15 has been amended to replace the phrase "allergic reaction" with the phrase "condition in need of treating and/or preventing." The latter phrase is recited in independent claim 1 from which claim 15 depends and thus provides antecedent basis for claim 15.

Dependent claims 46, 53, 55, 57, and 59 have been amended to clarify that the arithmetic mean steady state maximum plasma concentration (C_{max}) limitation simply recites a plasma concentration of 3-OH-desloratadine that is produced by the administration of desloratadine, which administration is recited in each independent claim from which claims 46, 53, 55, 57, and 59 respectively

depend. Applicants also have amended the article preceding this limitation in claims 46, 53, 55, 57, and 59 from "the" to "an."

Dependent claims 46, 53, 55, 57, and 59 also have been amended to clarify that the arithmetic mean time to maximum plasma concentration (T_{max}) limitations and the area under the concentration-time curve limitations in these dependent claims relate to 3-OH-desloratadine, not desloratadine. These limitations therefore are consistent with the independent claims from which claims 46, 53, 55, 57, and 59 depend. The maximum plasma concentration (T_{max}) limitation and area under the concentration-time curve limitation in those independent claims relate to desloratadine, not 3-OH-desloratadine.

Finally, dependent claim 49 has been amended to clarify that the arithmetic mean steady state maximum plasma concentration (C_{max}) limitation, the arithmetic mean time to maximum plasma concentration (T_{max}) limitation, and the area under the concentration-time curve limitation simply recite 3-OH-desloratadine plasma concentration characteristics produced by the administration of desloratadine, which administration is recited in independent claim 48, from which claim 49 depends. Applicants also have eliminated the use of the article "the" with these limitations.

The above-referenced amendments merely address the Examiner's concerns regarding the wording of the claims as originally submitted. No new matter has been added, and the amendments are fully supported by the specification.

C. Rejections Under 35 U.S.C. § 103

Claims 1-18, 24-28, and 31-59 stand rejected under 35 U.S.C. § 103(a) as being obvious in light of U.S. patent no. 5,962,464 ("Handley") and U.S. patent no. 5,595,997 ("Aberg"). The Office Action stated that:

(1) "since Handley and Aberg establish that the efficacy of DCL is dependent upon dosage, it would have been obvious to one of ordinary skill in the art to further modify the methods of Handley and Aberg such that DCL is administered in an amount and for a time that is effective to optimize its effect;" and

(2) "because both Handley and Aberg disclose administration of desloratadine at a dosage amount claimed by Applicant, the resulting mean plasma concentrations of desloratadine and its metabolite, 3-OH-desloratadine, would have been obvious."

Office Action at 9.

Applicants respectfully disagree with the Examiner's rejection of claims 1-18, 24-28, and 31-59 under section 103(a). In order to render a claimed invention obvious, the prior art must teach or suggest *all* of the claim limitations. *Manual of Patent Examining Procedure* ("MPEP"), §§ 2142 and 2143.03 (8th ed. 2000). As the Examiner noted, however, neither Handley nor Aberg discloses the blood plasma concentration profile-based method claimed by Applicants in the Application. *See* Office Action at 9.

In fact, neither Handley nor Aberg suggests *any* particular modification to their teachings, much less the particular method of safe and effective administration of desloratadine claimed by Applicants. Thus, Handley and Aberg cannot render the claimed invention obvious, because those references do not teach or suggest the *particular* claimed invention, *including all the claim limitations*. *See* MPEP § 706.02(j); *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995) ("'[O]bvious to try' has long been held not to constitute

obviousness. A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out.") (citations omitted).

The disclosure of certain suggested desloratadine dosages in Handley and Abert does not change this conclusion. Claims 1-18, 24-28, and 31-59 of the Application are directed to methods of treating allergic and inflammatory conditions by administering desloratadine in a manner sufficient to produce specified desloratadine and/or 3-OH-desloratadine blood plasma concentrations. Neither Handley or Aberg discloses any motivation or suggestion to focus on blood plasma concentrations of desloratadine and 3-OH-desloratadine, much less the specific concentration levels recited in the claims at issue. Nor does either Handley or Aberg teach or suggest any specific formulations or dosages needed to produce the relevant geometric or arithmetic mean steady state maximum plasma concentrations (C_{max}), geometric or arithmetic mean times to maximum plasma concentration (T_{max}), geometric or arithmetic mean steady state minimum plasma concentrations (C_{min}), or area under the concentration-time curve (0-24hr) values for the safe and effective treatment of the recited allergic or inflammatory conditions. Accordingly, Handley and Aberg do not render the claimed invention obvious. *See* MPEP §§ 706.02(j), 2142, and 2143.03; *Deuel*, 51 F.3d at 1559.

One of ordinary skill in the art would not have found it obvious to derive the claimed plasma concentration characteristics from the desloratadine dosages disclosed in Handley or Aberg. The pharmacokinetics of drugs is an unpredictable art. Plasma concentrations and characteristics of effective ingredients in drugs depend upon much more than the dosage of that ingredient.

They depend upon, among other things, the method of delivery (*e.g.*, injection, ingestion, sublingual absorption, inhalation), the form of the drug (*e.g.,* tablet, capsule, or liquid), and the composition of the drug (*e.g.,* amount of carrier or other compound in tablet, nature of coating in capsule, or concentration of solution) as well as other factors including, the extent and rate of the drug's absorption, distribution, binding or localization in tissues biotransformation or metabolism of the drug, and excretion of the drug. Thus, a 5 mg dose of desloratadine, depending upon the method of delivery, form, and composition of the drug and the other above-listed factors, could yield very different plasma concentrations and plasma concentration profiles. *See* ***Figure 1-1 on page 3*** *of* chapter 1(Leslie Z Benet, et al.), as well as pp. 3-29 of chapter 1 in Goodman & Gilman's, *The Pharmacological Basis of Therapeutics*, (9th ed. McGraw-Hill, 1996), attached as Appendix A; and *see also* ***Figure 1.1 on page 4*** *of* chapter. 1 (Anita C, Rudy, Ph.D. & D.Craig Brater, M.D.), as well as pp. 3-17 *of* chapter 1 in *The Pharmacologic Approach to the Critically Ill Patient,* (3rd ed., Williams &Wilkins, 1994), attached as Appendix B.

Handley and Aberg, however, do not suggest any particular method or vehicle for delivery of desloratadine. To the contrary, Handley and Aberg disclose the same desloratadine dosage range for all delivery methods and forms. Handley, at col. 6:lines 11-15; Aberg, col. 8: lines 35-39. Thus, instead of teaching or suggesting the plasma concentration profile-based invention claimed by Applicants, Handley and Aberg suggest instead that the important factor in administering desloratadine is total dosage.

Applicants therefore respectfully submit that no *prima facie* case of obviousness has been made. Nothing in Handley or Aberg, alone

or in combination, suggests the pharmokinetic profiles for desloratadine, or its active metabolite 3-OH-desloratadine, included in each of claims 1-18, 24-28, and 31-59. Applicants respectfully submit that claims 1-18, 24-28, and 31-59 are patentable over the references cited. Reconsideration and withdrawal of this ground of rejection are urged.

* * *

Applicants call the following co-pending, commonly-owned U.S. patent applications to the attention of the Examiner: (1) U.S. patent application serial no. 10/088,629, filed on March 19, 2002, which is a national stage application of international patent application no. PCT/US00/25609, filed on September 19, 2000, and which claims priority to U.S. patent application serial no. 09/400,599 (now abandoned), filed on September 22, 1999; and (2) U.S. patent application no. 10/088,708, filed on March 20, 2002, which is a national stage application of international patent application no. PCT/US00/25595, filed on September 19, 2000, and which claims priority to U.S. patent application serial no. 09/400,147 (now abandoned), filed on September 21, 1999.

If the under signed attorney for applicants can be of any assistance in advancing the prosecution of the Application, please call him at 908-298-5037.

Respectfully submitted,
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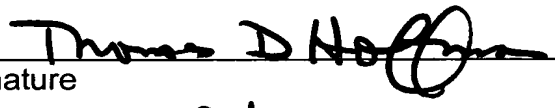
August 22, 2002

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

August 22, 2002
Date of Deposit

THOMAS D. HOFFMAN
Registered Representative



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VERSION OF AMENDED CLAIMS MARKED TO SHOW CHANGES

2. (Amended) The method of claim 1 wherein the geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine is produced at a desloratadine geometric mean T_{max} [is] in the range of about 1.60 to about 2.50 hours.

3. (Amended) The method of claim 1 wherein the arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine is produced at a desloratadine arithmetic mean T_{max} [is] in the range of about 2.54 to about 3.96 hours.

5. (Amended) The method of claim 4 wherein the geometric mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine is produced at a 3-OH-desloratadine geometric mean T_{max} [is] in the range of about 4.00 to about 6.25 hours.

6. (Amended) The method of claim 4 wherein the arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine is produced at a 3-OH-desloratadine arithmetic mean T_{max} [is] in the range of about 3.80 to about 5.95 hours.

11. (Amended) The method of claim 1 wherein a plot of the plasma concentration of desloratadine over time yields a [the] geometric mean AUC(0-24hr) for desloratadine [is] in the range of about 39.5 ng.hr/mL to about 61.8 ng.hr/mL.

12. (Amended) The method of claim 1 wherein a plot of the plasma concentration of desloratadine over time yields an [the] arithmetic mean AUC(0-24hr) for desloratadine [is] in the range of about 45.5 ng.hr/mL to about 71.1 ng.hr/mL.

13. (Amended) The method of claim 4 wherein a plot of the plasma concentration of 3-OH-desloratadine over time yields a [the] geometric mean AUC(0-24hr) for 3-OH-desloratadine [is] in the range of about 24.3 ng.hr/mL to about 38.0 ng.hr/mL.

14. (Amended) The method of claim 4 wherein a plot of the plasma concentration of 3-OH-desloratadine over time yields an [the] arithmetic mean AUC(0-24hr) for 3-OH-desloratadine [is] in the range of about 25.8 ng.hr/mL to about 40.4 ng.hr/mL.

15. (Amended) The method of claim 1 wherein the [allergic reaction] condition in need of treating and/or preventing is seasonal allergic rhinitis, perennial [perenninal] allergic rhinitis, atopic dermatitis, urticaria or allergic asthma.

17. (Amended) The method of claim 16 wherein the geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine is produced at a desloratadine geometric mean T_{max} [is] in the range of about 1.60 to about 2.50 hours.

18. (Amended) The method of claim 16 wherein the arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine is produced at a desloratadine arithmetic mean T_{max} [is] in the range of about 2.54 to about 3.96 hours.

19. (Amended) A method of treating and/or preventing seasonal or perennial allergic rhinitis in a human of 12 years and older which comprises administering an effective amount of [3-OH-]desloratadine for a time sufficient to produce a geometric mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine in the range of about 1.50 ng/mL to

about 2.34 ng/mL, or an arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine in the range of about 1.60 ng/mL to about 2.50 ng/mL.

20. (Amended) The method of claim 19 wherein the geometric mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine is produced at a 3-OH-desloratadine geometric mean T_{max} [is] in the range of about 4.00 to about 6.25 hours.

22. (Amended) The method of claim 19 wherein the arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine is produced at a 3-OH-desloratadine arithmetic mean T_{max} [is] in the range of about 3.80 to about 5.95 hours.

27. (Amended) The method of claim 16 wherein a plot of the plasma concentration of desloratadine over time yields a [the] geometric mean AUC(0-24hr) for desloratadine [is] in the range of about 39.5 ng.hr/mL to about 61.8 ng.hr/mL.

28. (Amended) The method of claim 16 wherein a plot of the plasma concentration of desloratadine over time yields an [the] arithmetic mean AUC(0-24hr) for desloratadine [is] in the range of about 45.5 ng.hr/mL to about 71.1 ng.hr/mL.

29. (Amended) The method of claim 19 wherein a plot of the plasma concentration of 3-OH-desloratadine over time yields a [the] geometric mean AUC(0-24hr) for 3-OH-desloratadine [is] in the range of about 24.3 ng.hr/mL to about 38.0 ng.hr/mL.

30. (Amended) The method of claim 19 wherein a plot of the plasma concentration of 3-OH-desloratadine over time yields an [the] arithmetic

mean AUC(0-24hr) for 3-OH-desloratadine [is] in the range of about 25.8 ng.hr/mL to about 40.4 ng.hr/mL.

31. (Amended) A method of treating and/or preventing atopic dermatitis or urticaria in a human of 12 years and older in need of such treating and/or preventing which comprises administering an effective amount of desloratadine for a time sufficient to produce a geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine in the range of about 2.90 ng/mL to about 4.54 ng/mL, or an arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine in the range of about 3.2 ng/mL to about 5.0 ng/mL.

32. (Amended) The method of claim 31 wherein the geometric mean steady state maximum plasma concentration (C_{max}) of desloratadine is produced at a desloratadine geometric mean T_{max} [is] in the range of about 1.60 to about 2.50 hours.

33. (Amended) The method of claim 31 wherein the arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine is produced at a desloratadine arithmetic mean T_{max} [is] in the range of about 2.54 to about 3.96 hours.

34. (Amended) A method of treating and/or preventing atopic dermatitis or urticaria in a human of 12 years and older in need of such treating and/or preventing which comprises administering an effective amount of desloratadine for a time sufficient to produce a geometric mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine in the range of about 1.50 ng/mL to about 2.34 ng/mL, or an arithmetic mean steady state

maximum plasma concentration (C_{max}) of 3-OH-desloratadine in the range of about 1.6 ng/mL to about 2.50 ng/mL.

35. (Amended) The method of claim 34 wherein the geometric mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine is produced at a 3-OH-desloratadine geometric mean T_{max} [of 3 OH-desloratadine is] in the range of about 4.00 to about 6.25 hours.

36. (Amended) The method of claim 34 wherein the arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine is produced at a 3-OH-desloratadine arithmetic mean T_{max} [of 3 OH-desloratadine is] in the range of about 3.80 to about 5.95 hours.

41. (Amended) The method of claim 31 wherein a plot of the plasma concentration of desloratadine over time yields a [the] geometric mean AUC(0-24hr) for desloratadine [is] in the range of about 39.5 ng.hr/mL to about 61.8 ng.hr/mL.

42. (Amended) The method of claim 31 wherein a plot of the plasma concentration of desloratadine over time yields an [the] arithmetic mean AUC(0-24hr) for desloratadine [is] in the range of about 45.5 ng.hr/mL to about 71.1 ng.hr/mL.

43. (Amended) The method of claim 34 wherein a plot of the plasma concentration of 3-OH-desloratadine over time yields a [the] geometric mean AUC(0-24hr) for 3-OH-desloratadine [is] in the range of about 24.3 ng.hr/mL to about 38.0 ng.hr/mL.

44. (Amended) The method of claim 34 wherein a plot of the plasma concentration of 3-OH-desloratadine over time yields an [the] arithmetic

mean AUC(0-24hr) for 3-OH-desloratadine [is] in the range of about 25.8 ng.hr/mL to about 40.4 ng.hr/mL.

45. (Amended) A method of treating and/or preventing the nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis and for treating chronic idiopathic urticaria in a human of 12 years and older in need of such treating and /or preventing which comprises administering to said human about 5.0 mg of desloratadine once a day for about 10 days to produce at a[n] desloratadine arithmetic mean time to maximum plasma concentration (T_{max}) of about 3 hours post dose, an arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic mean area under the concentration-time (0-24hr) curve of about 56.9 ng.hr/mL of desloratadine.

46. (Amended) The method of claim 45 wherein the administration of desloratadine produces an [the] arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine, [produced post dose] at an arithmetic mean time to maximum plasma concentration (T_{max}) of 3-OH-desloratadine of about 4.8 hours, [is] of about 2 ng/mL[,] and an arithmetic mean area under the concentration-time (0-24hr) curve of 3-OH-desloratadine [is] of about 32.3 ng.hr/mL.

48. (Amended) A method of treating and/or preventing the nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis and/or of treating chronic idiopathic urticaria in a human of 12 years and older in need of such treating and /or preventing which comprises administering an effective amount of desloratadine for a time sufficient to produce a steady state geometric mean maximum plasma concentration (C_{max}) of desloratadine in the range of

about 2.90 ng/mL to about 4.54 ng/mL at a geometric mean time to maximum plasma concentration (T_{max}) of desloratadine in the range of about 1.60 to about 2.50 hours post dose, or a steady state arithmetic mean maximum plasma concentration (C_{max}) of desloratadine in the range of about 3.2 ng/mL to about 5.0 ng/mL at an arithmetic mean time to maximum plasma concentration (T_{max}) of desloratadine in the range of about 2.54 to about 3.96 hours post dose.

49. (Amended) The method of claim 48 wherein the administration of desloratadine produces an arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine, [produced post dose] at an arithmetic mean time to maximum plasma concentration (T_{max}) of 3-OH-desloratadine in the range of about 3.80 hours to 5.95 hours, [is] in the range of about 1.60 ng/mL to about 2.50 ng/mL[,] and an arithmetic mean area under the concentration-time (0-24hr) curve of 3-OH-desloratadine [is] in the range of about 25.8 ng.hr/mL to about 40.4 ng.hr/mL.

52. (Amended) A method of treating and/or preventing the nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis and/or of treating chronic idiopathic urticaria in a human of 12 years and older in need of such treating and /or preventing which comprises administering to said human about 5.0 mg of desloratadine once a day for about 10 days to produce an arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL at an arithmetic mean time to maximum plasma concentration (T_{max}) of desloratadine of about 3 hours post dose.

53. (Amended) The method of claim 52 wherein the administration of desloratadine produces an arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine, [produced] at an

arithmetic mean time to maximum plasma concentration (T_{max}) of 3-OH-desloratadine of about 4.8 hours [post dose], [is] of about 2.0 ng/mL[,] and an arithmetic mean area under the concentration-time (0-24hr) curve of 3-OH-desloratadine [is] of about 32.3 ng.hr/mL.

54. (Amended) A method of treating and/or preventing the nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis and/or of treating chronic idiopathic urticaria in a human of 12 years and older in need of such treating and /or preventing which comprises administering to said human about 5.0 mg of desloratadine once a day for about 10 days to produce at a[n] desloratadine arithmetic mean time to maximum plasma concentration (T_{max}) of about 3 hours post dose, an arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic mean area under the concentration-time (0-24hr) curve of about 56.9 ng.hr/mL of desloratadine.

55. (Amended) The method of claim 54 wherein the administration of desloratadine produces an arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine, [produced] at arithmetic mean time to maximum plasma concentration (T_{max}) of 3-OH-desloratadine of about 4.8 hours [post dose], [is] of about 2.0 ng/mL[,] and an arithmetic mean area under the concentration-time (0-24hr) curve of 3-OH-desloratadine [is] of about 32.3 ng.hr/mL.

56. (Amended) A method of treating chronic idiopathic urticaria in a human of 12 years and older in need of such treating and /or preventing which comprises administering to said human about 5.0 mg of desloratadine once a day for about 10 days to produce at a[n] desloratadine arithmetic mean

time to maximum plasma concentration (T_{max}) of about 3 hours post dose, an arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic mean area under the concentration-time (0-24hr) curve of about 56.9 ng.hr/mL of desloratadine.

57. (Amended) The method of claim 56 wherein the administration of desloratadine produces an arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine, [produced] at arithmetic mean time to maximum plasma concentration (T_{max}) of 3-OH-desloratadine of about 4.80 hours [post dose], [is] of about 2.0 ng/mL[,] and an arithmetic mean area under the concentration-time (0-24hr) curve of 3-OH-desloratadine [is] of about 32.3 ng.hr/mL.

58. (Amended) A method of treating and/or preventing the nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis in a human of 12 years and older in need of such treating and /or preventing which comprises administering to said human about 5.0 mg of desloratadine once a day for about 10 days to produce at a[n] desloratadine arithmetic mean time to maximum plasma concentration (T_{max}) of about 3 hours post dose, an arithmetic mean steady state maximum plasma concentration (C_{max}) of desloratadine of about 4 ng/mL, and an arithmetic mean area under the concentration-time (0-24hr) curve of about 56.9 ng.hr/mL of desloratadine.

59. (Amended) The method of claim 58 wherein the administration of desloratadine produces an arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine, [produced] at arithmetic mean time to maximum plasma concentration (T_{max}) of 3-OH-desloratadine of about 4.80 hours [post dose], [is] of about 2.0 ng/mL[,] and an

arithmetic mean area under the concentration-time (0-24hr) curve of 3-OH-desloratadine [is] of about 32.3 ng.hr/mL.